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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,878	01/17/2006	5515154	067448-0000004	1031

24201 7590 12/21/2006

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 12/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/007,878*.

PATENT NO. *5515154*.

ART UNIT *3993*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/007,878	Patent Under Reexamination 5515154	
	Examiner Sara S. Clarke	Art Unit 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☐ Responsive to the communication(s) filed on _____. b☐ This action is made FINAL.
c☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☒ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims 1-23 are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☒ Claims 6,7 and 16 are patentable and/or confirmed.
4. ☒ Claims 1-5,8-15 and 17-23 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. _____.
   4☐ been filed in reexamination Control No. _____.
   5☐ been received by the International Bureau in PCT application No. _____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

DETAILED ACTION

Statutory Bases for Claim Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. **Claims 1-3, 8-11, and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,922,905 to Strecker ("Strecker") in view of EP Patent App. 540,290 A2 to Advanced Cardiovascular Systems ("ACS").

2. The subject matter of claims 1 and 23 of the subject patent is not fully supported by the parent applications. More specifically, the parent applications do not provide support for the following recitation in claims 1 and 23 of the subject patent: "a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter." Thus, claim 1, the claims that depend thereon,

and claim 23 are not entitled to the benefit of the filing date of the parent applications. ACS was published (May 5, 1993) more than one year prior to the filing date of application, which matured into the subject patent. Since claims 1-11 and 23 are not entitled to the effective filing date of the parent applications, ACS is applicable against these claims under 35 U.S.C. 102(b). See MPEP 201.11(I)(B).

3. Regarding claim 1, Strecker discloses the invention substantially as claimed including an outer wall surface at 30' on a cylindrical element 20', said outer wall surface being smooth prior to expansion of said stent (Fig. 8) and forming a plurality of outwardly projecting edges 34 (Fig. 9) which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. See col. 9, ll. 17-21.

4. Regarding claims 2 and 3, see col. 9, ll. 14-21, and Figs. 8 and 9.

5. Regarding claim 8, see col. 8, ll. 33-38, which discloses that the configuration of Figs. 8 and 9 is fixable at a predetermined expansion site.

6. Regarding claim 11, see col. 3, l. 60.

7. Regarding claim 23, Strecker discloses an outer wall surface having a plurality of outwardly projecting edges 34 (Fig. 9) which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. See col. 9, ll. 17-21.

8. Strecker does not disclose a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis; and a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other, as is required in claims 1 and 23. Strecker further does not disclose said stent being formed of a

biocompatible material selected from the group of materials consisting of stainless steel, tantalum, NiTi alloys, and thermoplastic polymers (claim 9); and said stent being formed from a single piece of tubing (claim 10).

9. ACS discloses a plurality of cylindrical elements 12 which are independently expandable in the radial direction. See col. 5, ll. 7 and 8. As disclosed in the abstract, ll. 5-8, elements 12 are interconnected so as to be generally aligned on a common longitudinal axis. ACS further discloses a plurality of connecting elements 13 for interconnecting said cylindrical elements 12, said connecting elements 13 configured to interconnect only said cylindrical elements 12 that are adjacent to each other. See col. 4, ll. 36 and 37. As discussed at col. 1, l. 51- col. 2, l. 14, the configuration of ACS, including independently expandable cylindrical elements 12 and connecting elements 13, results in a structure, which is both flexible along its length and stiff in the radial direction such that it is able to resist collapse.

10. ACS also teaches making its tubing of stainless steel, tantalum, NiTi alloys, and thermoplastic polymers because these materials are biocompatible. See col. 7, ll. 23-26.

11. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of Strecker, including its outwardly projecting edges, such that it has a plurality of independently expandable cylindrical elements, each interconnected only to adjacent cylindrical elements by connecting elements, as taught by ACS for the purpose of providing a structure, which is both flexible along its length and stiff in the radial direction such that it is able to resist collapse; and such that it has is made of stainless steel, tantalum, NiTi alloys, or thermoplastic polymers because these materials are biocompatible.

12. **Claims 1, 4, 5, 8-10, and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over ACS in view of Strecker.

13. Regarding claim 1, ACS discloses the invention substantially as claimed including a plurality of cylindrical elements 12 which are independently expandable in the radial direction (col. 5, ll. 7 and 8) and which are interconnected so as to be generally aligned on a common longitudinal axis (see Fig. 4); a plurality of connecting elements 13 for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other (see Fig. 4); and an outer wall surface on said cylindrical elements. As discussed at col. 2, l. 12, the configuration of ACS is flexible along its length.

14. Regarding claims 4 and 5, see Fig. 5.

15. Regarding claim 8, see col. 2, ll. 47-52.

16. Regarding claim 9, see col. 7, ll. 24-26.

17. Regarding claim 10, see the abstract, l. 4 and col. 3, ll. 3-6.

18. Regarding claim 23, ACS discloses a plurality of cylindrical elements 12 which are independently expandable in the radial direction (col. 5, ll. 7 and 8) and which are interconnected so as to be generally aligned on a common longitudinal axis (see Fig. 4); a plurality of connecting elements 13 for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other (Fig. 4); an outer wall surface on said cylindrical elements, said outer wall surface having a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter, whereby said stent does not substantially shorten upon expansion from said first diameter

to said second, larger diameter (col. 3, ll. 10-15).

19. ACS does not disclose said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter (claim 1) and said outer wall surface having a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter (claim 23).

20. Strecker discloses an outer wall surface at 30' on a cylindrical element 20', said outer wall surface being smooth prior to expansion of said stent (Fig. 8) and forming a plurality of outwardly projecting edges 34 (Fig. 9) which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. See col. 9, ll. 17-21. The formation of outwardly projecting edges 34 assures a form-fit fixation of the endoprosthesis in the vessel wall. See col. 9, ll. 19-21.

21. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of ACS, such that it has outwardly projecting edges, which form as the stent is radially expanded, as taught by Strecker for the purpose of 34 assuring a form-fit fixation of the endoprosthesis in the vessel wall.

22. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over ACS as modified by Strecker, as applied to claim 1 above, and further in view of US Patent No. 3,526,005 to Bokros et al. ("Bokros").

23. As discussed at paragraphs 12-21 above, ACS and Strecker disclose the invention of claim 1 substantially as claimed. However, ACS does not disclose said stent being coated with a biocompatible coating and Strecker does not provide a motivation for

providing the stent of ACS with a biocompatible coating.

24. Bokros discloses an intravascular prosthesis having an impervious isotropic pyrolytic carbon coating. As described at col. 4, ll. 47-49, the coating is biocompatible. As described at the Abstract, the coating contributes substantial strength to the composite prosthetic device.

25. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of ACS, as modified by Strecker, to include a coating as taught by Bokros for the purpose of strengthening the device.

26. **Claims 1, 3, 4, and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over the Mirich journal article "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" ("Mirich") in view of the Rösch journal article "Experimental Intrahepatic Portacaval Anastomosis: use of Expandable Gianturco Stents" ("Rösch").

27. Regarding claim 1, Mirich discloses the invention substantially as claimed including a plurality of cylindrical elements (see Fig. 1) which are independently expandable in the radial direction (see Fig. 1b) and which are interconnected so as to be generally aligned on a common longitudinal axis (see Fig. 1); a plurality of connecting elements for inter-connecting said cylindrical elements (see Fig. 1b, annotated), and said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other; and an outer wall surface on said cylindrical elements.

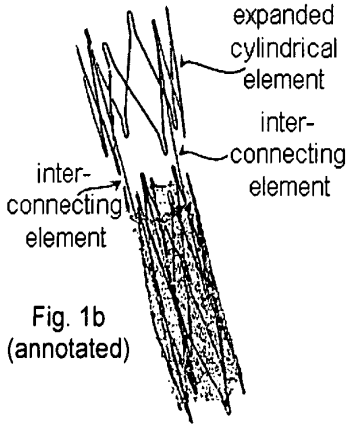

Fig. 1b (annotated)

28. Regarding claim 4, see Figs. 1a-c.

29. Regarding claim 9, see pg. 485, col. 1, l. 36.

30. Mirich does not disclose said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. Nor does Mirich show the outwardly projecting edges extending radially outwardly from the outer wall.

31. Rösch discloses said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. As noted at pg. 482, first column, the stent shown in Rösch is introduced within a sheath. The sheath is removed and the stent expands. In the sheath, the stent is unexpanded and is "smooth" since the skirt and the remainder of the stent are restrained to the same diameter by the sheath. Upon removal of the sheath, as per the description at pg. 482, the stent expands. Figs. 2c and d show the stent without the sheath. The skirt has flared radially outwards such that the stent is no longer "smooth." That is, the skirt and the remainder of the stent no longer have the same diameter. As discussed at pg. 483, the use of a skirt helps to achieve proper positioning.

32. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of Mirich to include the skirts taught by Rösch such that the stent is smooth prior to expansion of said stent and forms a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter for the purpose of achieving proper positioning.

33. **Claims 1, 3, 4, and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirich in view of the Lawrence journal article "Percutaneous Endovascular Graft:

Experimental Evaluation" ("Lawrence").

34. As noted at paragraphs 27-29 above, Mirich discloses the inventions of claims 1, 4, and 9 substantially as claimed. However, Mirich does not disclose said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. Nor does Mirich show the outwardly projecting edges extending radially outwardly from the outer wall.

35. Lawrence discloses an expandable stent having an outer wall surface, which is smooth prior to expansion of said stent and which forms a plurality of outwardly projecting edges, which edges form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. As noted at pg. 357, third column, ll. 24-49, the grafts were introduced with the technique previously described for placement of a Gianturco stent (3)," making reference at footnote (3) to the Wright article "Percutaneous endovascular stents: an experimental evaluation." This article discloses the stent being compressed before introduction, and expanding after removal of said sheath. As noted at pg. 357 of Lawrence, second column, ll. 9-14 from the bottom, the stent shown in Lawrence is introduced within a sheath. The sheath is removed and the stent expands. See Fig. 1c. In the sheath, the stent is unexpanded and is "smooth" since the skirt and the remainder of the stent are restrained to the same diameter by the sheath. Upon removal of the sheath, as per the description at pg. 482, the stent expands. See pg. 357, second column, ll. 9-14 from the bottom, which disclose that after the device is released from the catheter, the internal stents open the Dacron tubing. Figs. 1b shows the stent without the sheath. The skirt has flared radially outwards such that the stent is no longer "smooth." That is, the

skirt and the remainder of the stent no longer have the same diameter. As discussed at pg. 357, the use of a skirt helps to anchor the graft.

36. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of Mirich to include the skirts taught by Lawrence such that the stent is smooth prior to expansion of said stent and forms a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter for the purpose of achieving anchoring.

37. **Claims 12, 13, 17, 19, and 21** are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,104,404 to Wolff ("Wolff").

38. Wolff discloses the invention as claimed including a longitudinally flexible stent. Fig. 2 shows the stent flexed longitudinally. The articulated stent of Wolff comprises a plurality of cylindrical elements 12. Fig. 6 shows that the stent segments are capable of expanding independently to fit in a vessel having a change in diameter. Said elements 12 are interconnected (via hinges 14) so as to be concentrically aligned on a common longitudinal axis as shown in Fig. 1. A plurality of generally parallel connecting elements 14 interconnect said cylindrical elements. Fig. 1 of Wolff shows that the connecting elements 14 are configured to interconnect only said cylindrical elements that are adjacent to each other.

39. Claim 12 further requires that the connecting elements are configured to interconnect only said cylindrical elements that are adjacent to each other, so that said stent, when expanded radially outwardly, retains its overall length without appreciable shortening. The specification of the subject patent provides the following guidance regarding the configuration of connecting elements that causes the stent to retain its

overall length without appreciable shortening when the stent is expanded radially outwardly. At the very bottom of col. and the top of col. 3, the subject patent discloses, "Preferably, all of the interconnecting elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which for[m] the stent. In this manner there is no shortening of the stent upon expansion." At col. 5, ll. 48-51, subject patent discloses, "all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during expansion thereof." The subject patent makes no reference to any of the drawings to illustrate which particular configuration shows all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements. Since Wolff discloses its connecting elements 14 connected at only peaks and valleys, it appears that Wolff discloses identical structure to that disclosed in the subject patent for performing the claimed function. Thus, it appears that Wolff meets the limitation of having a configuration of connecting elements that causes the stent to retain its overall length without appreciable shortening when the stent is expanded radially outwardly.

40. Regarding claim 13, at per col. 1, ll. 54 and 55, Wolff discloses the use of the stent segments disclosed in US Patent No. 4,830,003 to Wolff et al. (" '003 patent"). When the stent elements in the '003 patent are released in position, they spring back to their normal, uncompressed position. See col. 3, ll. 1-18. Since the normal, uncompressed position is also the expanded position, the stent elements of Wolff are capable of retaining their expanded condition upon the expansion thereof.

41. Regarding claim 17, Fig. 1 shows the connecting elements are circumferentially

displaced with respect to the longitudinal axis.

42. Regarding claim 19, Wolff discloses the use of a single hinge between adjacent cylindrical elements. This single hinge falls in the claimed range of up to four.

43. Regarding claim 21, since the product in this product-by-process claim is anticipated by the product of Wolff, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113 regarding product-by-process claims.

44. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,344,053 to Boneau ("Boneau") in view of Wolff.

45. Boneau discloses the invention substantially as claimed including a plurality of cylindrical elements (see col. 6, ll. 6-19) each having a diameter and a length. Claim 14 further requires that the radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof. At col. 5, ll. 4-22, Boneau discloses that the typical vessel, into which the stent of Boneau might be implanted ranges from 1.5 mm to 5 mm in diameter. Thus, since the cylindrical element of Boneau is expanded to the vessel diameter (see Fig. 4), the diameter of the cylindrical element of Boneau, upon inflation of the expandable member, ranges from 1.5 mm to 5 mm. Boneau also discloses that corresponding stents may range from 1 mm to 2 cm in length. Since Boneau discloses a range of diameters, which is greater than the disclosed range of lengths, it would have been obvious to one of ordinary skill in the art at the time of invention to make the stent of Boneau with the radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof. See MPEP 2144.05.

46. Regarding claim 15, Boneau discloses the use of stainless steel at col. 4, l. 48.

47. Boneau does not disclose a longitudinally flexible stent, comprising a plurality of

interconnected cylindrical elements aligned along a common longitudinal axis, and upon radial expansion the stent retains its overall length without appreciable shortening, as required in claim 12.

48. Wolff discloses a longitudinally flexible stent arrangement having interconnected cylindrical elements aligned along a stent longitudinal axis as shown in Fig. 1. Based upon the structure disclosed in the subject patent for performing the function of not appreciably shortening upon radial expansion of the stent (see col. 3, ll. 9-13, and col. 5, ll. 53-56), which discloses connecting to either peaks or valleys, since the cylindrical elements of Wolff are connected by connectors at only peaks or valleys, it appears that the configuration of Wolff meets this functional limitation. As shown in Fig. 2, the arrangement of Wolff is longitudinally flexible. This arrangement, as described at col. 1, ll. 47-52, permits articulation and maintains the spacing between adjacent segments.

49. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the stent arrangement of Boneau with interconnections as taught by Wolff for the purpose of permitting articulation, maintaining the spacing between adjacent segments, and placing the tandem stents in vessels that curve in different directions.

50. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff.

51. Wolff discloses the invention substantially as claimed with the exception of the stent being formed from a single piece of tubing. Instead, Wolff discloses a plurality of welded together wires. However, as disclosed at col. 1, l. 55-58, the stent segments from '003 are merely illustrative. The subject patent does not attribute any new or unexpected results to forming the stent of a single piece of tubing. Thus, it would have been a matter of obvious design choice to one of ordinary skill in the art at the time of invention to make the device

of Wolff of a single, integral piece since the subject patent does not attribute any new or unexpected results to forming the stent of a single piece of tubing. See MPEP 2144.04(V)(B).

52. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff in view of Bokros.

53. As discussed at item 38 and 39 above, Wolff discloses the invention of claim 12 substantially as claimed. However, Wolff does not disclose said stent being coated with a biocompatible coating.

54. Bokros discloses an intravascular prosthesis having an impervious isotropic pyrolytic carbon coating. As described at col. 4, ll. 47-49, the coating is biocompatible. As described at the Abstract, the coating contributes substantial strength to the composite prosthetic device.

55. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Wolff to include a coating as taught by Bokros for the purpose of strengthening the device.

56. **Claims 12 and 17-20** are rejected under 35 U.S.C. 102(b) as being anticipated by the Furui journal article "Hepatic Inferior Vena Cava Obstruction: Treatment of Two Types with Gianturco Expandable Metallic Stents" ("Furui").

57. Regarding claim 12, Furui discloses the invention as claimed including a longitudinally flexible stent as shown in Fig. 2c. Fig. 2c shows multiple stents in tandem conforming to the curve of a curved vessel. Furui further shows a plurality of cylindrical elements, which are independently expandable in the radial direction. Furui discloses that the individual cylindrical elements are Gianturco stents. As disclosed in U.S. Patent No.

5,305,706 to Gianturco et al. (cited in the IDS submitted May 30, 2006), a Gianturco stent is formed of a stainless steel wire arranged in a closed, zig-zag pattern, and is more fully described in US Pat. No. 4,580,568 to Gianturco (cited in the same IDS). Since the individual cylindrical elements are Gianturco stents, which expand upon removal of the sheath, and they are connected at only two opposite circumferential locations, the individual cylindrical elements of Furui appear to expand independently at least to some degree. As shown in Fig. 1, the cylindrical elements of Furui are interconnected so as to be concentrically aligned on a common longitudinal axis. Since the cylindrical elements of Furui are connected by struts at only peaks or valleys, based upon the structure disclosed in the subject patent for performing the function of not appreciably shortening upon radial expansion of the stent (see item 39 above), it appears that the configuration of Furui meets this functional limitation.

58. Regarding claims 17-19, see Fig. 1 of Furui.

59. Regarding claim 20, see pg. 665, col. 2, last line and col. 3, ll. 4 and 5.

60. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Furui.

61. Claim 14 requires that the length of the radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof. Furui does not explicitly disclose a stent meeting this limitation. However, it does disclose stent segments having a length of 25 mm and a diameter range of 20-28 mm. See pg. 665, col. 2, last line and col. 3, first line. Since the claimed range of the diameter lies within the range disclosed by Furui, it would have been obvious to one of ordinary skill in the art at the time of invention to make the stent of Furui with the length of the radially expandable cylindrical

elements in an expanded condition less than the diameter thereof. See MPEP 2144.05.

62. Regarding claim 15, see pg. 665, col. 2, last line.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

63. **Claims 1, 2, and 4** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 7 of **US Patent No. 6,056,776**. Although the conflicting claims are not identical, they are not patentably distinct from each other because even though claims 6 and 7 of US Patent No. 6,506,776 do not recite an outer wall, the cylindrical rings of these claims inherently have outer wall surfaces. Moreover, since the projecting edges form upon expansion, by implication, prior to expansion, the outer wall surfaces are smooth since the projecting edges have not been formed. With respect to claim 4 of the subject patent, claims 6 and 7 of US Patent No. 6,506,776 recite an undulating pattern in the form of peaks and valleys, which is the same if not narrower than the claimed "serpentine pattern." Claims 6 and 7 of US Patent No. 6,056,776 do not recite the plurality of cylindrical elements being independently expandable, as recited in claim 1 of the subject patent. However, ACS teaches providing independently expandable cylindrical elements 12 to facilitate implantation of the stent in a variety of body lumen shapes. See col. 5, ll. 7-12. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of claims 6 and 7 of US Patent No. 6,506,776 to have independently expandable elements as taught by ACS for the purpose of facilitating implantation of the stent in a variety of body lumen shapes.

64. **Claims 1 and 2** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14, and 21 of **US Patent No. 5,728,158**. Although the conflicting claims are not identical, they are not patentably distinct from each other because every element recited in claims 1 and 2 of the subject patent is also recited in claims 1, 14, and 21 of US Patent No. 5,728,158 with the exception of the plurality of cylindrical elements being independently expandable, as recited in claim 1 of

the subject patent. However, ACS teaches providing independently expandable cylindrical elements 12 to facilitate implantation of the stent in a variety of body lumen shapes. See col. 5, ll. 7-12. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of 1, 14, and 21 of US Patent No. 5,728,158 to have independently expandable elements as taught by ACS for the purpose of facilitating implantation of the stent in a variety of body lumen shapes.

65. One-way obviousness analysis was applied above because it appears that the conflicting claims could have been filed in a single (*i.e.,* the earlier filed) application and it does not appear that there was an administrative delay. See MPEP 804(II)(B)(1)(a,b). However, in the event that the claims could not have been filed in a single application and there was administrative delay, the following rejection shows that claims 6 and 7 of US Patent No. 6,056,776 are obvious variations of the claims of the subject patent (two-way obviousness analysis).

66. Claims 6 and 7 of US Patent No. 6,056,776 are not patentably distinct from claim 4 of the subject patent because every element recited in claims 6 and 7 of US Patent No. 6,056,776 is also recited in claim 4 of the subject patent.

67. Claims 6 and 7 of US Patent No. 6,056,776 are not patentably distinct from claims 1 and 2 of the subject patent. Claims 1 and 2 of the subject patent do not recite an undulating pattern in the form of peaks and valleys. ACS discloses an undulating pattern in the form of peaks and valleys to provide for radial expansion by decreasing the wave's amplitude. See col. 2, ll. 28-43. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cylindrical elements of claims 1 and 2 of the subject patent such that the elements have an undulating pattern in the form of peaks and

valleys as taught by ACS for the purpose of allowing radial expansion.

Response to Requester's Proposed Rejections

68. At pages 18-22 of the request, the requester suggests that the Mirich journal article "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" ("Mirich") anticipates claims 1 and 4. The examiner disagrees. The claim includes a comparison of the smoothness of the outer wall surface of the cylindrical elements in both expanded and non-expanded configurations. It appears from Figs. 1a-c that the stents of Mirich are "smooth" prior to expansion only by way of the nylon covering. The actual outer surface of the stents themselves, *i.e.,* not including the nylon covering, appears to be equally as "smooth" in both the expanded and non-expanded configurations. The so-called "projecting edges" the requester refers to at page 21 of the request appear, to the examiner, to exist equally in both the expanded and non-expanded configurations. Moreover, the "projecting edges" referred to by the requester are not outwardly projecting as required by claim 1. The requester also refers to the barbs of Fig. 1c. The examiner notes that in the embodiment of Fig. 1c, because of the barbs, the stents appear to be equally as smooth in both the expanded and non-expanded configurations.

69. At pages 30-32 of the request, the requester suggests that US Patent No. 5,133,732 to Wiktor ("Wiktor") anticipates claim 12. The examiner disagrees because Wiktor does not disclose a plurality of cylindrical elements and a plurality of generally parallel connecting elements. With respect to the requirement for a plurality of cylin-drical elements, the requester relies on Fig. 12 (see page 30 of the request). However, this figure shows one continuous spiral and not a plurality of elements. At page 10 of the decision ordering reexamination, the examiner stated that Fig. 8 shows a plurality of

sections. However, upon reconsideration, the examiner now concedes that construing randomly chosen sections of a coil as a plurality of cylindrical sections, as shown in the figure at page 10 of the decision, is not a reasonable position to take. With respect to the requirement for a plurality of generally parallel connecting elements, the first embodiment of Wiktor (Fig. 7) discussed by the requester at page 31, only shows one interconnected element. The second embodiment of Wiktor (Fig. 8), discussed by the requester at page 31, does not appear to show generally parallel connecting elements.

Statement of Reasons for Patentability and/or Confirmation

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

70. Regarding **claims 6 and 7**, the prior art does not show, singly or in combination, the combination of elements recited in this claim including members tipping radially outwardly to form said outwardly projecting edges upon radial expansion of the stent.

71. Regarding **claim 16**, the prior art does not show, singly or in combination, the combination of elements recited in this claim including the connecting elements between adjacent elements being in axial alignment.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not

to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 5,514,154 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Any paper filed with the Office, *i.e.,* any submission made, by either the patent owner or the third party requester **must** be served on every other party in the reexamination proceeding in the manner provided by § **1.248**. The document must reflect service or the document may be refused consideration by the Office. See 37 CFR 1.550(f).

The patent owner is notified that any proposed amendments to the specification and/or claims in this reexamination proceeding **MUST** comply with 37 CFR 1.530(d)-(j), 37 CFR 1.52(a) and (b), and 37 CFR 1.20(c).

Contact Information

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:

By **U.S. Postal Service Mail**: Mail Stop *Ex Parte* Reexam
Attn: Central Reexamination Unit
Commissioner for Patents

P. O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-9900
Central Reexamination Unit

By hand: Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulany Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

Sara Clarke
Primary Examiner
Central Reexamination Unit
(571) 272-4873

Index of Claims

Application/Control No.	Applicant(s)/Patent under Reexamination
90/007,878	5515154
Examiner	**Art Unit**
Sara S. Clarke	3993

√	Rejected	–	(Through numeral) Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claim		Date
Final	Original	12/13/06
	1	√
	2	√
	3	√
	4	√
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Bib Data Sheet

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90/007,878	01/17/2006 RULE	623	3993	067448-0000004

APPLICANTS

5515154, Residence Not Provided;
ADVANCED CARDIOVASCULAR SYSTEMS INC.(OWNER), SANTA CLARA, CA;
Jack S. Barufka(3rd. Pty. Req.), Mclean, VA;
Jack S. Barufka, Mclean, VA

** CONTINUING DATA ************************* verified [initials]

This application is a REX of 08/281,790 07/28/1994 PAT 5,514,154
which is a CIP of 08/164,986 12/09/1993 ABN
which is a CON of 07/783,558 10/28/1991 ABN

** FOREIGN APPLICATIONS ******************** none [initials]

Foreign Priority claimed / 35 USC 119 (a-d) conditions met / Verified and Acknowledged	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
Foreign Priority claimed ☐ yes ☒ no 35 USC 119 (a-d) conditions met ☐ yes ☒ no ☐ Met after Allowance Verified and Acknowledged [signature] Examiner's Signature Initials			23	3

ADDRESS

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TITLE

EXPANDABLE STENTS

FILING FEE RECEIVED	FEES	
2520	FEES: Authority has been given in Paper No. ________ to charge/credit DEPOSIT ACCOUNT No. ________ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other ________ ☐ Credit

Search Notes

Application/Control No.	Applicant(s)/Patent under Reexamination
90/007,878	5515154
Examiner	**Art Unit**
Sara S. Clarke	3993

SEARCHED

Class	Subclass	Date	Examiner
623	1.15	12/06	
606	108		
606	194		

INTERFERENCE SEARCHED

Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)

	DATE	EXMR
NONE	12/06	